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Please find below and/or attached an Office communication concerning this application or proceeding.

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BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Application Number: 10/036,202
Filing Date: December 27, 2001
Appellant(s): FLACK ET AL.

Benjamin C. Stasa
Registration No. 55,644
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 14 July 2008 appealing from the Office action mailed

11 February 2008.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

No amendment after final has been filed.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

NEW GROUND(S) OF REJECTION

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition
> of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the
> conditions and requires of this title.

Claims 10-18 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-

statutory subject matter. Under the statute, the claimed invention must fall into one of the four

recognized statutory classes of invention, namely, a process (or method); a machine (or system);

an article of manufacture; or a composition of matter. The latter three categories define "things"

or "products" while a process consists of a series of steps or acts to be performed. For purposes

of determining whether a process is eligible for patent under 35 U.S.C 101, a process has been

given specialized, limited meaning by the courts.

Under the guidance of Supreme Court precedent and recent Federal Circuit decisions, in order

for a process to be considered eligible for patent under 35 U.S.C. 101, the process must (1) be

tied to another statutory class or (2) transform underlying subject matter to a different state or

thing. If neither of these requirements is met by the claim, the process is not a patent eligible

process under 35 U.S.C. 101 and is accordingly rejected as being directed to non-statutory

subject matter.

Claim 10 recites a series of method steps directed to the defining of patient information,

calculating an estimated glomerular filtration rate for the patient, generating a treatment

recommendation, and calculating a treatment goal. The method steps presented in the body of the

claim fail to positively recite the use of a machine, article of manufacture, or a composition of

matter in achieving the desired result. As presently constructed, the recited method steps can be

accomplished purely by mental processing and are therefore not specifically enabled by another

recognized statutory class of invention.

While the Examiner recognizes that the preamble of claim 10 recites "a computer-

implemented....method..", nominal recitation of another statutory class presented exclusively in

the preamble of a process claim will not be awarded patentable weight when making

determinations of subject matter eligible for patent under 35 U.S.C. 101. Accordingly, claim 10

is rejected because it is directed to non-statutory subject matter under 35 U.S.C 101.

Claims 11-18, when analyzed in the same manner described above with respect to claim 10, also

fail to positively recite another statutory class of invention. Therefore, claims 11-18 are also

rejected under 35 U.S.C. 101 as being directed to non-statutory subject matter.

(8) Evidence Relied Upon

2004/0260666   Pestotnik et al.   12-2004

2003/0019115   Tannenbaum   1-2003

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

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Under the guidance of Supreme Court precedent and recent Federal Circuit decisions, in order

for a process to be considered eligible for patent under 35 U.S.C. 101, the process must (1) be

tied to another statutory class or (2) transform underlying subject matter to a different state or

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fail to positively recite another statutory class of invention. Therefore, claims 11-18 are also

rejected under 35 U.S.C. 101 as being directed to non-statutory subject matter.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all

obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in
> section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are
> such that the subject matter as a whole would have been obvious at the time the invention was made to a person
> having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the
> manner in which the invention was made.

[1]   Claims 1-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pestotnik et

al. (United States Patent Application Publication #2004/0260666) in view of Tannenbaum

(United States Patent Application Publication #2003/0019115).

[A]   As per claim 1, Pestotnik et al. teaches a patient healthcare management system having a

capability to evaluate patient kidney function (Pestotnik et al.; Abstract, paragraphs [0024]

[0085]), the system configured to: receive input defining a patient's medical record including the

patient's demographic information, medical condition and diagnosis (Pestotnik et al.; paragraphs

[0010] [0024] [0083] [0085]); output at least one medical treatment recommendation wherein the

recommendation is based on the patient's medical record (Pestotnik et al.; Abstract and

paragraphs [0084] [0085] [0131]) and calculate and output at least one treatment goal for the

patient (Pestotnik et al.; paragraphs [0094] [0150] [0151]).

[i]   The Pestotnik et al. system and method gathers patient data and evaluates the patient data

to identify known or unknown medical conditions and provide decision-supported data to a

physician including guidance as to the potential medical conditions of the patient and to aid the

clinician in making informed decisions related to patient medical care (Pestotnik et al.;

paragraphs [0011] [0017] [0018]). Among the outputs of the Pestotnik system are at least one

medical diagnosis and at least one medical care recommendation that are based upon a large

expert knowledge base (Pestotnik et al.; paragraph [0022]). Pestotnik et al. further disclose that

the expert knowledge base is constructed from information and data from experts within the

relevant fields of medicine including Renal diseases (Pestotnik et al.; paragraph [0085]). While

Pestotnik et al. specifically disclose an expert knowledge base constructed to accommodate

diagnosis and treatment of renal diseases, Pestotnik et al. fail to specifically disclose well-known

clinical indicators such as Glomerular Filtration Rate that are commonly associated with renal

diseases or compromised renal function.

[ii]   However, as evidenced by Tannenbaum, the use of calculators to determine Glomerular

Filtration Rate (GFR) from patient data as entered into well-known equations such as the

Cockcroft-Gault equation or variants thereof (as disclosed by Applicant), is well-known in the art

(Tannenbaum; Abstract and paragraphs [0025]-[0036] and [0047]).

[iii]   It would have been obvious to one of ordinary skill in the art at the time the invention

was made to have combined the teachings of Pestotnik et al. with those of Tannenbaum. Such a

combined system and method would have referenced an expert knowledge base to evaluate

entered the patient data to identify known or unknown medical conditions and provide decision-

supported data to a physician including guidance as to the potential medical conditions of the

patient and to aid the clinician in making informed decisions related to patient medical care

(Pestotnik et al.; paragraphs [0011] [0017] [0018] [0085]). Further, such a system-enabled

method, when specifically configured to assist a physician in diagnosing and treating renal

diseases, would have included in the expert knowledge base, calculators/equations for providing

information on well-known clinical indicators such as Glomerular Filtration Rate (GFR) as

determined by well-known equations such as the Cockcroft-Gault equation and commonly

employed variants thereof (Tannenbaum; Abstract and paragraphs [0025]-[0036] and [0047]).

The motivation to combine the teachings would have been to assist nephrologists and other

healthcare professionals in correctly prescribing doses of medications in patients with renal

impairment (Tannenbaum; paragraph [0013]).

[B]   As per claim 2, Pestotnik et al. teaches a system wherein the at least one treatment goal

for the patient comprises at least one of: a goal blood pressure, a goal lipid level, a goal

cholesterol level and a goal hemoglobin A1C level (Pestotnik et al.; paragraphs [0094] [0127]).

[C]   As per claim 3, Pestotnik et al. teaches a system additionally configured to receive input

specifying a treatment for the patient (Pestotnik et al.; Abstract and paragraph [0067] [0076])

[D]   As per claim 4, Pestotnik et al. teaches a system additionally configured to output an

indication as to whether, based on the patient's medical record, the at least one medical treatment

goal has been met (Pestotnik et al.; paragraphs [0094] [0151]).

[E]   As per claim 5, Pestotnik et al. teaches a system wherein a plurality of clinical treatment

algorithms are applied to the patient's medical record to generate the at least one treatment

recommendation and the at least one patient treatment goal (Pestotnik et al.; paragraphs [0084]

[0094] [0138] [0150] [0151]).

[F]   As per claim 6, Pestotnik et al. teaches a system additionally configured to: receive input

specifying a patient's current medication(s); receive input specifying a new prescription for the

patient (Pestotnik et al.; paragraph [0153]); and generate an alert if the prescribed medication

may antagonize a medication the patient is currently taking (Pestotnik et al.; paragraphs [0077]

[0154]).

[G]   As per claim 7, Pestotnik et al. teaches a system further configured to: receive input

defining a plurality of patient medical records comprising patient demographic information,

medical condition, diagnosis and treatment (Pestotnik et al.; paragraphs [0010] [0024] [0083]

[0085] [0116]); receive input defining at least one medical record parameter to extract from the

plurality of medical records (Pestotnik et al.; paragraph [0112]); and automatically generate a

report containing an aggregate of the at least one medical record parameter extracted from the

plurality of medical records (Pestotnik et al.; paragraphs [0026] [0094]).

[H]   As per claim 8, Pestotnik et al. teaches a system further configured to receive input

defining a subset of the plurality of patient medical records from which to extract the at least one

medical record parameter (Pestotnik et al.; paragraphs [0112] [0153]).

[I]   As per claim 9, Pestotnik et al. teaches a system additionally configured to receive input,

for each patient encounter with his or her healthcare provider (Pestotnik et al.; paragraphs [0127]

[0145]) defining the patient encounter wherein each defined patient encounter is appended to the

patient's medical record (Pestotnik et al.; paragraphs [0127] [0128]).

[i]   Regarding claims 2-9, the obviousness and motivation as discussed with regard to claim 1

above are applicable to claims 2-9 and are herein incorporated by reference.

[J]   Claims 10-18 differ from system claims 1-9 in that claims 10-18 are directed to a method.

As per this element, Pestotnik et al. teaches both a method and a system (Pestotnik et al.;

paragraphs [0012]-[0118] and [0027]).

[i]   The remainders of claims 10-18 repeat the same limitations of system claims 1-9, and are

therefore rejected for the same reasons given for those claims.

[K]   As per claim 19, Pestotnik et al. teaches a computer-based system for interactively

managing patient healthcare and evaluating patient kidney function, the system comprising: a

means for defining a patient's medical record (Pestotnik et al.; paragraphs [0010] [0024] [0083]

[0085]); a means for generating at least one patient treatment recommendation based on the

patient's medical record (Pestotnik et al.; Abstract and paragraphs [0084] [0085] [0131]) and a

means for calculating at least one treatment goal for the patient (Pestotnik et al.; paragraphs

[0094] [0150] [0151]).

[i]   As discussed above with regard to claim 1, while Pestotnik et al. specifically disclose an

expert knowledge base constructed to accommodate diagnosis and treatment of renal diseases,

Pestotnik et al. fail to specifically disclose well-known clinical indicators such as Glomerular

Filtration Rate (estimated or otherwise) that are commonly associated with renal diseases or

compromised renal function.

[ii]   However, as evidenced by Tannenbaum, the use of calculators to determine Glomerular

Filtration Rate (GFR) (as a function of serum creatine, age, and weight) from patient data as

entered into well-known equations such as the Cockcroft-Gault equation or variants thereof (as

disclosed by Applicant), is well-known in the art (Tannenbaum; Abstract and paragraphs [0025]-

[0036] and [0047]). Accordingly, Tannenbaum discloses a means for calculating the patient's

estimated glomerular filtration rate based on the patient's medical record (Tannenbaum;

paragraphs [0025]-[0036] [0047]).

[iii]   Regarding claim 19, the obviousness and motivation to combine as discussed with regard

to claim 1 above are applicable to claim 19 and are herein incorporated by reference.

Response to Remarks

Applicant's remarks filed 21 November 2007 have been fully considered but they are not

persuasive. The remarks will be addressed below in the order in which they appear in the

response filed 21 November 2007.

Applicant remarks that the combination of Pestotnik and Tannenbaum, does not describe the

system defined by claim 1 of present application.

(10) Response to Argument

In the Appeal Brief filed 14 July 2008, Appellant makes the following arguments:

(A)   Pestotnik et al. fail to disclose a system configured to calculate and output at least one

treatment goal for the patient.

(B)   One of ordinary skill in the art would not have had reason to combine the teachings of

Pestotnik and Tannenbaum.

(C)   Tannenbaum does not teach the means for establishing the patient's estimated glomerular

filtration rate based on the patient's medical record.

Examiner will address the Appellant's arguments in sequence as they appear in the Brief.

Argument (A):

In response to Appellant's first argument that Pestotnik et al. fail to disclose a system configured

to calculate and output at least one treatment goal for the patient, Examiner directs Appellant's

attention to the applied teachings of Pestotnik at paragraphs [0094] [0150] and [0151] and

secondarily to the supportive teachings of Pestotnik at paragraphs [0138] and [0174].

As a general overview, Pestotnik et al. disclose a system-enabled method that includes receiving

patient data, evaluating the data to produce decision-supported data including medical condition

diagnosis, medical parameters for the medical condition, and medical care recommendations

(Pestotnik et al. Abstract).

Of note are the "pertinent medical parameters" disclosed by Pestotnik et al. Specific reference to

the medical parameters for the patient's medical condition are provided in the examples provided

by Pestotnik et al. In particular, at paragraph [0094], Pestotnik et al. indicates in exemplary

fashion that the pertinent medical parameters for a patient with diabetes include gathering the

"most recently acquired heart rate, blood pressure, blood sugar level, and the like, while

providing warnings to the clinician" (Pestotnik et al. paragraph [0094]). Examiner interprets the

specific parameters associated with each patient/disease to include symptoms such as high blood

pressure or abnormal blood sugar levels. Examiner further interprets the warnings/alerts to the

physician that are generated upon analysis of the blood pressure readings to indicate that the

patient's blood pressure is too high or blood sugar levels are unhealthy. Pestotnik et al. indicate

that a treatment regimen is then recommended based on the input pertinent medical parameters

and patient data for those parameters (i.e., blood pressure etc.). While Examiner notes that

Pesotnik fails to explicitly indicate that a "treatment goal is defined", it would be obvious to one

or ordinary skill in the art the Pestotnik is determining/calculating at least one treatment goal by

alerting the physician that the patient's blood pressure is too high and subsequently

recommending a treatment (e.g. blood pressure medication) with the obvious intention of

lowering the patient's blood pressure.

In further support of the Examiner's position, Examiner notes the applied teachings of Pestotnik

at paragraphs [0151]. At paragraph [0151], Pestotnik indicates that patient data is periodically

updated and analyzed to determine if the current treatment regime is successfully treating the

condition. Examiner maintains that it is implicit from this statement and would be obvious to one

of ordinary skill in the art that Pestotnik is evaluating patient symptoms (i.e. pertinent medical

parameters) and determining if the treatment is successfully alleviating the symptoms (i.e.

treatment goal).

Lastly, Examiner directs Appellant's attention to the supportive teachings of Pestotnik at

paragraph [0138] in which Pestotnik indicates that in addition to the treatment recommendation,

the system provides a "probability of success for curing the disease" with the treatment regimen.

Examiner further submits that the probability of success for curing the disease (i.e., alleviating

the symptoms) additionally constitutes calculating a treatment goal, at least insofar as claimed by

Appellant.

Argument (B):

In response to Appellant's second argument, Examiner initially directs Applicant's attention to

the teachings of Pestotnik, which include expert knowledge base to evaluate entered patient data

to identify known or unknown medical conditions and provide decision-supported data to a

physician including guidance as to the potential medical conditions of the patient and to aid the

clinician in making informed decisions related to patient medical care (Pestotnik; paragraphs

[0011][0017][0018][0085]). Further, Pestotnik indicates that the disclosed system stores medical

"information from experts within the relevant fields of medicine", such as...Renal diseases

(Pestotnik; paragraph [0085]).

Secondarily, Examiner directs Applicant's attention to the teachings of Tannenbaum which

include well known calculation devices and equations for determining a patient's estimated

glomerular filtration rate as calculated from body weight, sex, and age entered into well known

equations such as the Cockcroft-Gault equation (as utilized by Applicant) and derivations thereof

(Tannenbaum; Abstract and paragraphs [0025]-[0036] and [0047]).

Of note, Examiner directs Appellant's attention to paragraph [0074] of Pestotnik in which

Pestotnik indicates that disclosed system is operable on a computer, hand held devices, or any

programmable consumer electronic device. Similarly, while Appellant correctly notes that

Tannenbaum discloses a slide rule, Tannenbaum further discloses that the equation can be run on

a hand held processing device or calculator (Tannenbaum; paragraph [0047} and Fig. 6).

Examiner notes that the combination of Pestotnik and Tannenbaum requires only fully disclosed

and publicly available programming of the same device.

Examiner maintains that the equation and calculations disclosed by Tannenbaum constitute

"information derived from experts in the field" as clearly indicated by Pestotnik to be considered

source information for the Pestotnik expert system. Further, the rules-based expert system

disclosed by Pestotnik does not preclude the use of data (i.e. pertinent medical parameters)

derived from well known equations that are commonly applied to the evaluation and diagnosis of specific diseases (i.e., Renal disorders), merely because Pestotnik applies if-then reasoning to making diagnoses and treatment recommendations. In conclusion, Examiner considers the combination to constitute applying a known technique (i.e., calculation of glomerular filtration rate as disclosed by Tannenbaum) to a known device ready for improvement (Pestotnik) to yield predictable results.

Arguments (C):

In response to Appellant's third argument, Examiner notes that Appellant has not invoked 112 6th paragraph previously in prosecution but has done so only on appeal.

Examiner notes that Appellant correctly indicates that Tannenbaum "provides a slide ruler and calculator for calculating the Glomerular Filtration Rate (GFR) or the patient…" Examiner notes that Tannenbaum further discloses a hand held electronic device that performs the same calculations. With respect to this argument, Appellant appears to argue that the Tannenbaum performs the calculations disclosed by Appellant but does not derive the input information from the patient's medical record.

Examiner agrees that the Tannenbaum manually inputs of the data elements (i.e., height, weight etc.) into the calculating device. Although the argument is not entirely clear to the Examiner,

Examiner assumes Appellant is arguing that the data in Tannenbaum are not derived via a

computer network from an electronic medical record.

Nevertheless, Examiner's rejection relies on the structure provided by the primary reference

Pestotnik et al. which includes a computer network accessible patient record for the

collection/input of data used in determining diagnosis and treatment recommendation for the

patient (Pestotnik et al.; paragraphs [0010] [0024] [0083]). Examiner's rejection is only reliant on

Tannenbaum for the specific teaching of the commonly known Cockcroft-Gault equation and

derivations thereof for calculating a patient glomerular filtration rate.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related

Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

This examiner's answer contains a new ground of rejection set forth in section **(9)** above.

Accordingly, appellant must within **TWO MONTHS** from the date of this answer exercise one

of the following two options to avoid *sua sponte* **dismissal of the appeal** as to the claims subject

to the new ground of rejection:

(1) **Reopen prosecution.** Request that prosecution be reopened before the primary

examiner by filing a reply under 37 CFR 1.111 with or without amendment, affidavit or other

evidence. Any amendment, affidavit or other evidence must be relevant to the new grounds of

rejection. A request that complies with 37 CFR 41.39(b)(1) will be entered and considered. Any

request that prosecution be reopened will be treated as a request to withdraw the appeal.

(2) **Maintain appeal.** Request that the appeal be maintained by filing a reply brief as set

forth in 37 CFR 41.41. Such a reply brief must address each new ground of rejection as set forth

in 37 CFR 41.37(c)(1)(vii) and should be in compliance with the other requirements of 37 CFR

41.37(c). If a reply brief filed pursuant to 37 CFR 41.39(b)(2) is accompanied by any

amendment, affidavit or other evidence, it shall be treated as a request that prosecution be

reopened before the primary examiner under 37 CFR 41.39(b)(1).

Extensions of time under 37 CFR 1.136(a) are not applicable to the TWO MONTH time

period set forth above. See 37 CFR 1.136(b) for extensions of time to reply for patent

applications and 37 CFR 1.550(c) for extensions of time to reply for ex parte reexamination

proceedings.

Respectfully submitted,

/R. DAVID RINES/

Examiner, Art Unit 3626

/C Luke Gilligan/

Supervisory Patent Examiner, Art Unit 3626

A Technology Center Director or designee must personally approve the new

ground(s) of rejection set forth in section (9) above by signing below:

/Wynn W. Coggins/

Director, TC 3600

Conferees:

/CLG/

C. Luke Gilligan

S.P.E, A.U 3626

/VM/

Vincent Millin

Appeals Practice Specialist